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K010721
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510(K) SUMMARY

Submitted by:
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

February 28, 2001

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. Contact Person

Mr. Praveen Nadkarni
Phone: (732) 321-4950 Fax: (732) 321-4841

2. Device Name and Classification

Trade Name:	AXIOM *ARTIS* Modular Angiography System
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1600
Device Class:	Class II
Device Code:	90JAA

3. Intended Use

AXIOM *ARTIS* is a dedicated angiography system developed for single and biplane diagnostic imaging and interventional procedures.
AXIOM *ARTIS* can support the acquisition of position triggered imaging for spatial data synthesis. When equipped with the AXIOM OR table from the Koordinat Table family, the Modular Angiography System is suitable for angiographic procedures in operating rooms.

4. Substantial Equivalence

AXIOM *ARTIS* is substantially equivalent to the current, commercially available Siemens Angiographic systems, the Coroskop Hi-P, and the Polystar. The Coroskop Hi-P was described in premarket notification K940484 and received FDA clearance on April 19, 1994. The Polystar was described in premarket notification K913120 which received FDA Clearance on August 16th, 1991.

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in Attachment 4.

5. **Device Description**

The AXIOM *ARTIS* Modular Angiography System is designed as a set of components that may be combined into different configurations to provide specialized angiography systems

The new modular system consists of three basic stand variations, single plane floor mounted stand, second plane ceiling mounted stand, floor mounted multi-purpose stand, to satisfy the positioning and patient accessibility requirements of each specialized angiographic application, in addition to other key components.

The modified stand designs provide the basic building block upon which other components are selected (eg. Generator, x-ray tube, collimator etc.), and configured to allow a specific cardiac application.

6. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

Many of the components(Generator, X-ray tube, Imaging system, Collimators) used in the AXIOM *ARTIS* family are either commercially available with current Siemens systems or include minor modifications to existing components.

AXIOM *ARTIS* goes one-step beyond the currently available systems to create modular units with component commonality, streamlined user interface and use, and performance and reliability improvement.

7. **General Safety and Effectiveness Concerns**

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

8. **Substantial Equivalence**

In the opinion of Siemens Medical Systems, Inc., the hardware and software documentation and the substantial equivalence comparison matrix proves that the AXIOM *Artis* family of Modular Angiography systems is substantially equivalent to the Siemens Medical Systems, Inc. predicate Angiography systems - Angiostar Plus, Multistar Plus and Neurostar Plus systems.

Kathleen Rutherford

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

3/9/01
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2001

Ms. Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Ave. South
ISELIN NJ 08830

Re: K010721
Axiom Artis Modular Angiography System
(MP, FA, FC, BA, BC)
Dated: March 9, 2001
Received: March 12, 2001
Regulatory Class: II
21 CFR §892.1600/Procode: 90 IZI

Dear Ms. Rutherford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

510(k) Number (if known): K010721

Device Name: AXIOM *ARTIS* Modular Angiographic System

Indications for Use:

AXIOM *ARTIS* is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures.

Procedures that can be performed with the AXIOM *ARTIS* family include cardiac angiography, neuro-angiography, general angiography, operating room angiography, multipurpose angiography and radiographic/fluoroscopic procedures eg. Gastro-intestinal imaging, Skeletal imaging etc. AXIOM *ARTIS* can also support the acquisition of position triggered imaging for spatial data synthesis.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

David C. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010721